

REMARKS

By this amendment, claims 11-15, 19, 20, and 22-28 have been amended and no claims have been canceled. Accordingly, claims 11-17, 19, 20, and 22-28 remain in the application.

Applicant appreciates the allowance of claims 11-17, 19, 20, and 22-28 subject to compliance with the examiner's objections concerning the drawings and specification. The changes that have been made to the claims by this paper are intended to clarify the terminology that has been used and do not involve the addition of new matter. For example, the word "flexible" has been added to claim 11 to distinguish the flexible drape from the top drape. Dependent claims 12-15 have been amended to be consistent with the amendment to claim 11. Similar clarifying amendments have been made to claims 19, 20, and 24-28.

With respect to the drawings and specification, applicant has amended the specification to refer to the patient by reference numeral 10, while the drape now is referred to by reference numeral 12. This change avoids the need to amend the drawings since they use the reference numerals 10 and 12 to identify the patient and the drape, respectively.

Reference numerals have been added to the specification so that each element is consistently referred to by its proper reference numeral. Also, the abdominal drape 30 with adhesive strip 32 shown in FIG. 10 now is referred to by the alternate designation of "top drape." This amendment provides support for the language used in the claims. In addition, the adhesive on the bag 4, the adhesive on the drape 12, and

the removable layer for the adhesive are shown in amended FIG. 3 and are identified by reference numerals 24, 26, and 28, respectively.

None of the amendments to the drawings and specification involve the addition of new matter. Moreover, these amendments address each of the examiner's objections and are believed to place the case in condition for allowance.

CONCLUSION

The application now should be in condition for allowance. If the examiner has any remaining questions, he is requested to telephone the undersigned attorney in order to expedite prosecution of the application.

Respectfully submitted,

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Dated: May 5, 2009

SURGICAL DRAPING SYSTEM

BACKGROUND OF THE INVENTION

[0001] The present invention relates to a sterile surgical draping system for use during surgical procedures. The system could be used, for example, in surgeries on the perineal area, including but not limited to the buttocks, vaginal area, anal area, and upper thighs, or on the torso and upper extremities, including the head and arms. Many procedures are performed in combination with abdominal surgery or solely surgical intervention of these areas, in which case the area requires a sterile, surgical field. Currently, after the patient is placed on the operating table appropriately for surgery, sheets are pushed under the patient which results in random sterilization and in adequate isolation of the patient from the surgical table. The system provides a method of surgery in which, instead of forcing a sheet underneath a patient's buttocks, shoulder, or head, for example, a drape according to the present invention is placed under the patient prior to surgery, and extended to isolate the area of surgical interest from an operating table surface, including operating table extensions, such as leg, shoulder, or head boards.

SUMMARY OF THE INVENTION

[0002] The draping system of the present invention isolates the surgical area in a sterile fashion and in a manner that overcomes problems with current methods of draping. The draping system includes a sterile flexible drape, made of cloth, plastic, or paper for example, which is folded, preferably, in an accordion fashion, and placed in a sealed bag. The bag preferably is elongated for placing

across an operating table or operating surface. The bag also preferably is perforated so that it can easily be torn open or an edge can be separated from the main portion of the bag.

[0003] The folded drape, optionally enclosed in a bag, is laid across the operating table, for example, prior to placing the patient on the table. The patient is then placed on the table so that the folded drape lies beneath the patient. In a surgical procedure involving a perineal area, for example, the folded drape would be located near the lower lumbar spine region. After the patient has been positioned properly and prepped, the perforated portion of the bag, which is available for access near the edge of the table, is then opened, preferably simply by pulling by hand, to withdraw the interior accordion sterile drape from the inner portion of the bag. The drape is pulled out so that it covers the table in the area of surgical interest and covers substantially the portion of the operating table down to the floor. Sterile leggings are then placed over the legs of the patient, or in the case of an upper extremity procedure, over one or more of the patient's arm. A top drape with an adhesive strip, for example an abdominal drape with adhesive at the pubic area, also is provided. At the termination of the procedure, the draping system components are discarded. Perforations in the drape are provided to simplify separation and removal of contaminated portions of the drape from those portions of the drape likely to remain in place.

BRIEF DESCRIPTION OF THE DRAWINGS

[0004] Fig. 1 is a perspective view showing the surgical drape according to an exemplary embodiment of the present invention provided on a surgical table within its original container, with perforations indicated along the leading edge of the sealed package.

[0005] Fig. 2 illustrates the sterile, accordion-folded surgical drape shown in Fig. 1 partially withdrawn from the original container.

[0006] Fig. 3 illustrates an operating room table with the surgical drape of the present invention laying fully extended over the end of the operating table.

[0007] Fig. 4 illustrates a patient being placed on top of the folded surgical drape ~~with the patient's legs in stirrups to facilitate surgery in the local area.~~

[0008] Fig. 5 illustrates the surgical drape being pulled from its container after the perineum of the patient has been prepped.

[0009] Fig. 6 illustrates the surgical drape in place and fully extended.

[0010] Fig. 7 illustrates the surgical drape in place with leg covers placed over the patient's legs.

[0011] Fig. 8 illustrates a leg or arm cover according to an exemplary embodiment of the present invention.

[0012] Fig. 9 illustrates the cover of Fig. 8 collapsed for packaging.

[0013] Fig. 10 illustrates an abdominal drape according to an exemplary embodiment of the present invention.

DETAILED DESCRIPTION OS THE PREFERRED EMBODIMENTS

[0014] Referring to Fig. 1, a surgical drape assembly 2 is shown. The assembly 2 includes a flexible drape [[10]] 12. The drape [[10]] 12 is made of flexible material, such as cloth, plastic, paper, or other material capable of being provided or rendered sterile for use in a surgical operating arena. The drape 12 is of sufficient length and width to cover an end of an operating table 8. The drape 12 is provided in a folded condition, preferably, in an accordion fashion to compact the drape 12 along its length. The width of the drape 12 extends beyond the side edges of the operating table 8. The drape 12 optionally is placed in a long, narrow sealed bag 4, which can be placed across the end of the operating table 8 so that it hangs down either side of the table 8. Bag 4 is provided with perforations 6 for ease of tearing open or separation of the edge from the main portion of the bag 4.

[0015] Referring to Figs. 1-7, a method of using the perineal surgical drape assembly 2 is described. A patient 10 (Figs. 4-7) is not shown in Figs. 2 and 3 for clarity of illustration. The drape [[10]] 12, optionally contained within sealed bag 4, initially is laid widthwise across surgical table 8 prior to placing [[a]] the patient 10 on the table. See Fig. 1. One or more strips of tape or adhesive 24,26 can be provided on the exterior of

the bag 4 or on the drape 12 to aid in securing the bag 4 and/or the drape 12 to the operating table 8. The patient 10 is then placed on the table 8 so that the folded drape 12 lies at the lower lumbar spine region at the edge of the table 8. See Fig. 4. After the patient 10 has been positioned properly and prepped, the perforated portion 6 of the bag 4, which is on the edge of the table 8, or the drape 12 itself, is then pulled to withdraw the sterile drape 12 from the inner portion of the bag 4. An extension or handle 14 is provided on the leading edge of the drape 12 for ease of deployment. See Figs. 2 and 5.

[0016] Drape 12 is pulled out so that its length covers the table 8 in the area of surgical interest and then covers substantially the entire end of the table 8 down toward the floor, as shown in Figs. 3 and 6. The drape 12 can provide sterile protection underneath the patient's buttocks, and extend from beneath the patient 10 toward the floor, or the bag 4 itself can provide sterile protection under the patient 10, with the drape 12 providing the remainder of the sterile environment. An adhesive strip 26 can be provided along one or more edges of the drape 12 to secure the drape 12 and prevent slipping. The adhesive strips 24, 26 preferably are protected prior to use by a removable film 28. At least one line of perforations 17 is provided across the drape 12. Perforations 17 allow for tearing away a soiled portion of the drape 12 after completion of the surgical procedure, whereby a lower leg portion of the table 8 can be

extended to support the patient's legs on an unsoiled surface.

Advantageously, the drape 12 also allows for the optional attachment of a catch basin 19, made of plastic, for example, to the drape 12 under the area of surgery, to catch blood and other contaminants.

[0017] Referring to Fig. 7, the draping system of the present invention may include sterile leggings 16. Leggings 16 are placed over the legs of the patient 10, for example, after the patient 10 is placed in stirrups.

Leggings 16 can be enclosed with the rest of the draping system along with or in bag 4. An exemplary embodiment of the leg covers 16 according to the present invention is shown in greater detail in Figs. 8 and 9. The leg covers 16 are shaped like a stocking and have a mouth 18 that is round and open to fit easily over the patient's legs. Advantageously, a stiffener 20 preferably is provided at the mouth 18 of the leg cover 16 to allow the mouth 18 of the leg cover 16 to stay open to facilitate placement of the leg cover 16 over the patient's legs. Prior art leg covers generally are folded, flat, and unnecessarily difficult to slide over a patient's legs. Preferably, the leg covers 16 are at least partially enclosed at a foot end 22, opposite the mouth 18 of the leg cover 16, to cover the patient's feet. The leggings 16 can include perforations for ease of removal after the procedure. Fig. 9 illustrates the leg cover 16 as it is provided prior to surgery, collapsed for packaging. The leg cover 16 can be packaged, for example, in bag 4 with other components of the surgical draping system 2.

[0018] Referring to Fig. 10, an exemplary embodiment of an abdominal or top drape 30 of the draping system is illustrated. ~~Abdominal~~ Top drape 30 is a flat sheet with adhesive 32 attached on one end so that the adhesive 32 may be placed across the patient's lower pelvis during the draping, prior to surgery. The opposite end, without the adhesive 32, is extended towards the patient's head. The ~~abdominal~~ top drape 30 ~~[[lays]]~~ lies over the patient 10 and hangs down off the table 8 on either side. At the termination of the procedure, the drape ~~[[10]]~~ 12, leg covers 16, ~~abdominal~~ top drape 30, and bag 4 are discarded.

[0019] While the invention may be susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and have been described in detail herein. However, it should be understood that the invention is not intended to be limited to the particular forms disclosed. For example, although the invention has been described in connection with an exemplary embodiment as a perineal draping system, the system is easily adapted for use in other surgical procedures, such as those involving the arms and the head. In addition, the draping system can include various numbers of components, such as more than one drape, for example, for placement underneath either side of a patient in an abdominal procedure. Thus, the invention is to cover all modifications, equivalents, and

alternatives falling within the spirit and scope of the invention as defined by the following appended claims.